

Remarks

Claims 22-34 and 38-45 are pending in the subject application. Applicants acknowledge that claims 26-31 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have canceled claims 26-31 and added new claim 46. Support for the new claim can be found throughout the subject specification (see, for example, page 8, line 26 through page 9, line 26 and Example 1 (pages 22-34)). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 22-25, 32-34 and 38-46 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants gratefully acknowledge the Examiner's withdrawal of the objection to claim 22 and the rejection under 35 U.S.C. §§ 112, first and second paragraphs. Applicants also note that claims 32-34, 40, 41 and 45 do not appear to be rejected in this matter and clarification as to the status of these claims (*e.g.*, allowable, objected to, *etc.*) is requested.

Claims 22-25, 27, 28, 38, 39, and 42-44 are rejected under 35 U.S.C. § 103(a) as obvious over Boschetti (2002) in view of Xiang *et al.* (2001). The Office Action states that since IL-18BP is a protein, it would have been obvious for one skilled in the art to use the hydrophobic charge induction chromatography purification process as taught by Boschetti for the purification of IL-18BP. In addition, the Office Action indicates that one of skill in the art would have been able to modify the method of purification of IL-18BP because the hydrophobic charge induction chromatography (HCIC) represents an improvement towards achieving the ideal situation in the design of an antibody-selective sorbent since one skilled in the art would have expected success because IL-18BP has structural features similar to that of an immunoglobulin and methods of purifying antibodies with HCIC were successful in the art. Applicants respectfully assert that the claimed invention is not obvious over the cited references and that the Patent Office has failed to establish that the claimed invention is *prima facie* obvious.

In this regard, Applicants note that the Patent Office Examination Guidelines state:

- E. “Obvious To Try”—Choosing From a Finite Number of Identified, Predictable Solutions, With a Reasonable Expectation of Success

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office personnel must then articulate the following:

- (1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem;
- (2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem;
- (3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

In this case, Applicants respectfully submit that the Patent Office has failed to establish the *prima facie* obviousness of the claimed invention as the rejection of record fails to meet the requirements of either the KSR decision or the guidelines promulgated by the Patent Office. Namely, the Patent Office has failed to establish that there was a recognized problem or need in the art to solve a problem that would have motivated one to even try to purify IL-18BP using hydrophobic charge induction chromatography, that this solution was one of a finite number of identified, predictable solutions to the recognized need or problem or that one skilled in the art would have had a reasonable expectation of success in purifying IL-18BP using hydrophobic charge induction chromatography. Accordingly, reconsideration and withdrawal of the rejection of record is respectfully requested.

Additionally, the Office Action fails to establish that one skilled in the art would have had a reasonable expectation of success in purifying IL-18BP, on the basis of the cited references, or that one skilled in the art would have been motivated to combine the teachings of the cited references. It is noted that the Office Action states that “Xiang *et al.* teach that approximately 60% of the mature human IL-18BP **resembles an immunoglobulin (Ig) domain** that includes a highly conserved pair of cysteines and tryptophan residues and that IL-18BP was purified from a cell culture supernatant” (emphasis added). Applicants note that the cited reference does not teach that this segment of the mature IL-18BP is an Ig domain; rather, 60% of human IL-18BP **resembles** an Ig domain. Further, the cited reference indicates that the predicted Ig domain of IL-18BP has only about 25% amino acid

sequence identity with a similar domain within the IL-1 receptor (page 17380, column 2, first full paragraph) and the cited teaching provides no guidance as to the degree of similarity the IL-18BP has with immunoglobulin molecules or domains thereof. Thus, it is unclear that one skilled in the art would have had a reasonable expectation of success in purifying IL-18BP or that one skilled in the art would have been motivated to utilize hydrophobic charge induction chromatography, on the basis of the cited references, because the similarity of IL-18BP to an immunoglobulin or immunoglobulin domain is unclear. Accordingly, reconsideration and withdrawal of the rejection of record is respectfully requested.

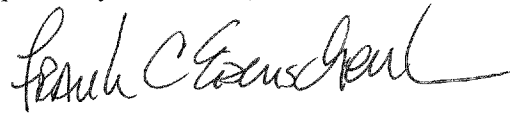
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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